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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,456	03/04/2002	Hanson S. Gifford	19196-001100	5104

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JENS E. HOEKENDIJK  
HOEKENDIJK & LYNCH, LLP  
P.O. Box 4787  
Burlingame, CA 94011-4787

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/090,456

Applicant(s)

GIFFORD ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-41 and 53-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-41 and 53-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

Claims 30 and 31 are objected to because of the following informalities:

-both claims lack antecedent basis for "the anchor".

It is suggested that the claims should depend from claim 29 instead of 26 to have proper antecedent basis for "the anchor". Appropriate correction is required.

Claim 37 is objected to because of the following informalities:

-the claim lacks antecedent basis for "the distal end".

It is suggested that the claim limitation should read --a distal end--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-33, 35-36, 38-41, 53-57, 59-60 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (US Pat# 5,782,904). White discloses a delivery catheter/retractable sheath (21) and a tubular liner (10) extending distally from the distal end of the catheter. See figure 4. The liner is moveable from a collapsed position to an expanded position. See 5:46+. The liner is releasably coupled to the delivery catheter. See 5:46+. The liner forms a through hole which receives a guidewire. See guidewire in figure 4 not labeled.

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The liner has an expandable metallic anchor (17) for moving the end of the liner toward the expanded position. See figures 6-7. The anchor is mounted to an expandable balloon section/inner tube (19) which expands the anchor. The inner tube (balloon) also has a through hole for receiving the guidewire. See figure 4. The balloon has a proximal portion (see figure 4) which extends beyond the anchor for occluding the vessel. The liner has at least two folded sections. See 5:15+; crimped tube of woven Dacron – non-metallic tube. The balloon has an inflation lumen (considered inherent for the balloon to be expanded as disclosed).

Regarding the dimensional limitations including the liner having a length of 2 cm; a length to diameter ratio of 20 to 1, 50 to 1, or 80 to 1; a diameter of 0.060 or 0.026 in; an expanded diameter of 4 mm; and a collapsed diameter of 0.020 to 0.032 in, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the liner of these dimensions. Applicant has not disclosed that these specific dimensions provide an advantage, are used for a particular purpose of solve a stated problem. Furthermore, one would have expected Applicant's invention to perform equally well with the dimensions as taught by White because the overall device performs the same function. Additionally, the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. The motivation for altering the dimensions of the prior art device would have been in order to accommodate different sized patients, such as children versus adults.

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Claims 26-27, 29-30, 32-33, 35-41, 53-57, 59 and 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al (US Pat# 5,360,443). Barone discloses a delivery catheter/retractable sheath (181/186) and a tubular liner (160) extending distally from the distal end of the catheter. See figures 1-4. The liner is moveable from a collapsed position to an expanded position. See 7:32+ and figures 1-4. The liner is releasably coupled to the delivery catheter. See figures 1 and 4. The liner has an expandable metallic anchor (172) for moving the end of the liner toward the expanded position. See figure 4. The anchor is mounted to an expandable balloon section/inner tube (183) which expands the anchor. The liner is covered by a coating (see 6:65). The liner has at least two folded sections. See folds in the figures 1-4. The balloon has an inflation lumen (considered inherent for the balloon to be expanded as disclosed). The liner is free at the second end. See figure 4.

Regarding the dimensional limitations including the liner having a length of 2 cm; a length to diameter ratio of 20 to 1, 50 to 1, or 80 to 1; a diameter of 0.060 or 0.026 in; an expanded diameter of 4 mm; and a collapsed diameter of 0.020 to 0.032 in, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the liner of these dimensions. Applicant has not disclosed that these specific dimensions provide an advantage, are used for a particular purpose of solve a stated problem. Furthermore, one would have expected Applicant's invention to perform equally well with the dimensions as taught by Barone because the overall device performs the same function. Additionally, the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not

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patentably distinct from the prior art device. The motivation for altering the dimensions of the prior art device would have been in order to accommodate different sized patients, such as children versus adults.

Claims 26-29, 32-36, 53-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quiachon et al (US Pat# 5,653,697). Quiachon discloses a delivery catheter/retractable sheath (101) and a tubular liner (11) extending distally from the distal end of the catheter. The liner is moveable from a collapsed position to an expanded position. The liner is releasably coupled to the delivery catheter. See 5:46+. The liner has an expandable metallic anchor (19) for moving the end of the liner toward the expanded position. See figures 5-6. The anchor is self expanding and has folds wrapped around one another. See figure 7. The liner has at least two folded sections. The device utilizes a guidewire and the liner has a through hole for receiving the guidewire. See 10:11+. The liner has a thickness of 0.012 in. See 4:50.

Regarding the dimensional limitations including the liner having a length of 2 cm; a length to diameter ratio of 20 to 1, 50 to 1, or 80 to 1; a diameter of 0.060 or 0.026 in; an expanded diameter of 4 mm; and a collapsed diameter of 0.020 to 0.032 in, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the liner of these dimensions. Applicant has not disclosed that these specific dimensions provide an advantage, are used for a particular purpose of solve a stated problem. Furthermore, one would have expected Applicant's invention to perform equally well with the dimensions as taught by Quiachon because the overall device performs the same function. Additionally, the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed

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relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. The motivation for altering the dimensions of the prior art device would have been in order to accommodate different sized patients, such as children versus adults.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat#s 5,843,160; 5,123,917; 5,158,548 and 5,843,158 teach analogous inventions in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*.  
June 1, 2004

*ANHTUAN T. NGUYEN*  
ANHTUAN T. NGUYEN  
PRIMARY EXAMINER  
*6/8/04*